



WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 12, 2006

Robert Held
Wellness Support Network
1449 Marion Drive
Glendale, California 91205

Dear Mr. Held:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.realfoodnutrients.com> and has determined that the product WSN® Diabetic Pack is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site include:

WSN® Diabetic Pack

- “Diabetes Breakthrough
Lower your blood sugar, safely and effectively with absolutely NO SIDE EFFECTS!!”
- “Nobel Prize winning technology validates WSN® Diabetic Pack ingredients! Studies show a **31.9%** drop in blood sugar levels!”
- “**The WSN® Diabetic Pack Breakthrough Benefits* Include:**
 - ✓ Lower Blood Glucose Levels ...
 - ✓ Lower Cholesterol Levels ...
 - ✓ Less Dependency on Medications”
- “Diabetes is a disease that if you don't take effective action against, it simply gets worse. Unfortunately, medications only treat the symptoms and usually do nothing to address the underlying causes. The good news is that cutting-edge science and

nutrition have come together to create a truly monumental and natural breakthrough for diabetics. ...The reason Foodform® technology works is because it operates at the

cellular level and addresses a key problem that every type 2 diabetic has. All type 2 diabetics have a deficiency of key nutrients the body needs to support healthy blood sugar levels. Your cells simply do not process blood sugar like they should. The WSN® Diabetic Pack helps your body metabolize blood sugar more efficiently.”

- “This study [of an herbal ingredient in WSN® Diabetic Pack] was done on type 2 diabetics (mildly insulin dependent) and reported **an average drop of blood glucose levels of 31.9% and average weight loss of 4.8 pounds in just 30 days!**”
- “The staff of Wellness Support Network have over 12 years of experience working with diabetics and the diabetic condition. ... We assist them in working out solutions to problems unique to their own case, to ensure they get the results we promise. ... Order your WSN® Diabetic Pack below and experience the results for yourself.”

Your web site also contains disease claims in the form of testimonials, including:

- “*My blood sugar went from 230 to 117 in just 21 days.*’ - *James Marshall, Georgia*”
- “*Barbara Culver, Michigan*
‘I was taking 50 units of insulin plus pills twice a day and my blood sugar just kept going up. I was tired all of the time and could fall asleep as soon as I sat down. I also kept gaining weight. Since I've been ... using the Diabetic Pack ... I have all kinds of energy and my sugar is down in the low 100s also I don't take insulin any more!’”
- “*Mike Corcoran, California*
‘About 60 days ago when I started your program my blood sugar count was at 332. My kidneys were in very poor condition Just today I was given my results from my last physical and can report that my blood sugar count is 117 and my kidney funtion[sic] is just slightly elevated above normal (which is a vast improvment [sic] from when I was first diagnosed). ... By the way, I forgot to mention... when I was first diagnosed, I weighed over 250 pounds and my blood pressure was high. I now weigh 193 pounds and my blood pressure is normal.’”

In addition, the name of your product suggests that it is intended for use in the cure, mitigation, treatment, or prevention of diabetes, a disease.

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a “new drug” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Your product “WSN® Diabetic Pack” is also

misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for this drug fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

Many of the above claims that make your product a drug were brought to your attention in a letter dated September 27, 2005, from Susan Walker, former Director of the Division of Dietary Supplement Programs in FDA's Center for Food Safety and Applied Nutrition, yet these claims still remain on your web site.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. While reviewing your web site, we noticed that you promote other products for disease treatment and/or prevention. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your web site, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be addressed to Kristen Moe, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you prefer to respond electronically, send your e-mail to kristen.moe1@FDA.HHS.GOV. If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition